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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,558	09/14/2001	Keiko Matsumoto	52740	7124

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,558	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,38 and 40-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,38 and 40-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment, Applicant's Arguments/Remarks, the request for extension of time (1 month-granted) and the Change of Attorney Address Notice, all filed 03/31/05 is acknowledged.

Claims 37, 38 and 40-57 are pending. Claims 37, 38, 41, 45 and 46 have been amended. New claims 47-57 have been added. Claims 1-36 and 39 have been cancelled. Claims 37, 38 and 40-57 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37, 38 and 40-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,480,175 in view of Kondo *et al.* (US Pat. No. 5,098,907) and further in view of Hunter *et al.* (US Pat. No. 5,733,578).

The GB reference teaches a pharmaceutical preparation in the form of coated tablets prepared by the direct compression of an active, wherein the composition comprises a lubricant, such as talc, magnesium stearate or stearic acid, an adjuvant, such as lactose or anhydrous calcium phosphate, and a disintegrant, such as starch (see column 3, lines 23-63). The tablet composition exhibits good compression characteristics, having no decrease of activity during the compressing step and has a desirable rate of disintegration (col. 3, lines 1-15).

The reference is silent as to the use of silicic anhydride and is silent regarding the angle of repose. With regards to the silicic anhydride, it is the position of the Examiner that one of ordinary skill in the art could substitute silicic anhydride with talc, magnesium stearate or the like, as they are acceptable equivalents of silicic anhydride. The selection of a known material based on its suitability for its intended use is obvious, absent a clear showing of unexpected results attributable to the Applicant's specific selection.

Regarding angle of repose, no criticality is observed in the angle of repose since a product is being claimed and it is the patentability of the product that must be established. Moreover, one skilled in the art can readily determine a suitable angle of repose. Such skill is also evident from the reference of Kondo *et al.*

Kondo *et al.* ('907) teach a powdery pharmaceutical composition comprising a fluidizer, light anhydrous silicic acid, that functions to improve the flowability of the composition, whereby the composition exhibits an angle of repose of 40° (see reference column 4, lines 11-

17); (column 7, lines 22-45) and Examples. The composition also contains excipients, such as starch, lactose, magnesium stearate and the like (col. 5, line 5 – col. 7, line 21). Kondo *et al.* teach at col. 7, lines 10-17, that by the addition of magnesium stearate and light silicic anhydride, an improvement in the flowability was observed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the light anhydrous silicic acid taught by Kondo *et al.* within the formulation of GB '175 if the intended purpose was to improve the overall flowability of the compressed formulation since Kondo *et al.* explicitly teaches a composition comprising light silicic anhydride, wherein an improvement in the flowability was observed by the addition of the silicic anhydride. The expected resulted would be a tablet formulation exhibiting improved flowability and disintegration, as similarly desired by the Applicant.

The GB patent and Kondo *et al.* patent do not teach the production of tablets by blending using a high speed mixer, wherein blending is carried out without heating, melting, dissolving or freezing.

Hunter *et al.* ('578) teach rapidly disintegrating, directly compressible solid dosage formulations formed under high shear mixing conditions, whereby suitable apparatus for carrying out the high shear mixing include high-speed mixers and high shear granulators. According to Hunter *et al.*, the shear conditions under which the ingredients are combined permit the formation of the homogeneous granulate, but do not break down the materials undergoing the processing. When the apparatus is operating under dry mixing conditions, it is capable of transforming solid dosage form ingredients under shear conditions into the homogeneous

mixture (see reference column 4, lines 12-44); (col. 5, lines 16-18); (col. 12, lines 11-42). A further advantage of employing high shear mixing is to increase tablet hardness (col. 6, lines 46-49).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the production methods utilizing high speed mixers taught by Hunter *et al.* within the GB and Kondo *et al.* patents, because Hunter *et al.*, teach solid dosage formulations based on the use of high speed mixers and teach that the use of high shear mixing conditions provide for the sufficient transformation of the active ingredient (*i.e.*, acetaminophen) and direct compression vehicle into a homogeneous granulate without degradation. The expected result would be a highly effective rapidly disintegrating tablet having enhanced physical properties in which degradation is avoided.

Response to Arguments

Applicant's arguments filed 03/31/05 have been fully considered.

Firstly, Applicant argued regarding the new matter rejection under 35 U.S.C. 132 for the phrase 'in the absence of a solvent', in which Applicant has amended the claim language to remove the cited phrase and obviate the new matter rejection. Accordingly, the rejection under 35 U.S.C. 132 has been withdrawn by virtue of the Amendment.

Secondly, Applicant argued regarding the 35 U.S.C. §112, first paragraph rejection of claims 19-46, in which the phrase 'in the absence of a solvent' has been removed. Accordingly, the 35 U.S.C. §112, first paragraph rejection has been withdrawn by virtue of the Amendment.

Thirdly, Applicant argued regarding the 35 U.S.C. 103(a) rejection of claims 19-46 over the GB ('175) reference in view of Kondo et al. (US '907) stating, "The present method uses a high speed mixer to thoroughly bend an active agent with a surface modifying material, without heating, melting, dissolving or freezing. Neither Kondo et al. nor GB '175 teach or suggest obtaining a tablet by the claimed method for producing a fast distintegrating tablet. The combination also fails to teach or suggest that such a method can produce a surface modified powder which has a flowability of at most 42° in terms of angle repose and thus enables direct tabletting. The Examiner's reading of the GB reference completely overlooks the requirement of the use of maltose in the GB method. Kondo does not teach the present method and shows methods using freezing and dissolving."

Applicants' arguments have been fully considered, but were not found persuasive. The teachings of the GB reference are discussed above. Admittedly, while the GB reference do not teach the particular angle of repose and silicic anhydride, Kondo *et al.* remedies this deficiency of the GB patent by teaching that it is well known to formulate powdery pharmaceutical composition comprising light anhydrous silicic acid, that functions to improve the flowability of the composition and the composition of Kondo *et al.* also exhibits a suitable angle of repose of 40° (see reference column 4, lines 11-17); (column 7, lines 22-45) and Examples. The GB '175 and Kondo *et al.* references do not explicitly teach the use of high speed mixers, such as instantly claimed. Hunter *et al.* has been cited to demonstrate that the use of high-speed mixers to formulate tablet preparations is known. Additionally, Hunter *et al.* employ tablet production methods in which substantial heating, melting, dissolving or freezing steps are not required. Hunter *et al.* also teach the use of high shear mixing conditions to produce a fast disintegrating

tablet (see, for instance, column 5, lines 16-17). Moreover, Examiner notes that the GB reference also initially recognizes tablets having desirable rates of disintegration (col. 3, lines 12-15). Hunter et al. recognize the advantages of using high-speed mixers, such as to increase tablet hardness and avoid degradation of the tablet during processing. With regards to the requirement of maltose in the GB reference, the Examiner notes that the instant claims utilize "comprising" claim language and thus, the inclusion of additional ingredients, asides from those recited, are permitted in the formulation. Applicants have not demonstrated that the addition of maltose would be detrimental to the formulation.

It is the position of the Examiner that Applicants have not presented any unexpected or unusual results using the methods of the instant invention, since the prior art recognizes, teaches and suggests formulations comprising similar compositions having similar ingredients, and utilizing similar methods as claimed by Applicant. Given the combined teachings of the GB, Kondo *et al.* and Hunter *et al.* references, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Thus, the instant invention remains obvious and unpatentable over the cited art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

June 14, 2005

THURMAN K. PAGE
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